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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,731

07/05/2005

E Lucile White

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NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

10/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/519,731

Applicant(s)

WHITE ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

1. The Preliminary Amendments filed 28 December 2004 and 26 September 2007 are acknowledged and entered.

### **General Informal Matters**

2. For future reference please note, upon arrival at the United States Patent and Trademark Office (i.e., USPTO, each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning coding and incorporation in to the Electronic File Wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/interview with applicant/applicants' representative, it is suggested that the following information be recited in the header of each page for any filing/response/amendment:

- a. Attorney Docket Number;
- b. First Applicant's name (e.g., Smith Jones et al.);
- c. Filing date for said application (e.g., 17 November 2002);
- d. Date of Office Action being responded to (e.g., 27 August 2006);
- e. Date of amendment/response (e.g., 27 April 2007); and
- f. Examiner's name (e.g., Dr. Kailash C. Srivastava).

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

3. Contrary to indication in the title page of the Preliminary Amendment filed 28 December 2004, the Application number assigned to instant application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/519,731. To aid in correctly correlating any papers for this application (i.e., 10/519,731), please ensure that this application number (i.e., 10/519,731) is accurately recited in all future correspondence with this Office.

4. This application is assigned to Dr. Kailash C. Srivastava in Art Unit 1657 at the United States Patent Trademark Office (i.e., USPTO). To aid in correlating any papers for this application (i.e., 10/519,731), all further correspondence regarding this application (10/519, 731) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

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### **Claims Status**

5. Claims 1-42 are pending.

### ***Election /Restriction***

6. This application contains the following groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

- Group I, consisting of claims 1-20 and 36, drawn to a method to inhibit bacterial growth;
- Group II, consisting of claims 21-26, drawn to another method, wherein the method is to kill a bacterium, wherein said bacterium is either a Gram positive , or a Gram negative bacterium;
- Group III, consisting of claims 27-35 drawn to yet another method, wherein said method is to inhibit bacterial FtsZ; and
- Group IV, consisting of claims 37-42 drawn to yet another method, wherein said method is to treat bacterial infection in an individual.

### **Inventions are Independent and Distinct**

7. The inventions listed as Groups I-IV, despite mentioning compound(s) of a certain structure, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the inventions in each of Groups I-IV mentioned above is different from other because the distinguishing special technical feature of each one of the groups is not the compound having a certain structure, which is merely a component in the step; the distinguishing technical feature is cause/effect relationship , which is different in each inventive group. E.g., invention in Group I is a method to inhibit bacterial growth (i.e., bacteriostatic effect), but the one in Group II is to kill the bacteria, i.e., a bactericidal effect). Similarly, inventive Group III invention calls for a method to inhibit FtsZ, but the one in Group IV us to treat an individual suffering from a bacterial infection . Thus, inventions in each of Groups I-IV do not share the same or similar technical feature. Furthermore, the method claimed in inventive group III is not a substantial improvement over the art-recognized information since inhibition of bacterial FtsZ is documented in the art (e.g., See, White, L. E. 2002. 2-

lkoxycarbonylaminopyridines: inhibitors of *Mycobacterium tuberculosis* FtsZ, Journal of Antimicrobial Chemotherapy, Volume 50, Pages 111–114). Since no special technical feature exists among the inventions in groups I-IV, there is no unity of invention.

### Species Election

8.. This application contains claims directed to methods comprising different compositions/ingredients having a variety of chemical structures.

The search for each of the above inventive ingredients is not co-extensive, particularly with regard to the literature search. This is because of the fact that the inventive groups discussed above incorporate numerous compositions/ingredients of a variety of chemical structures and bacterial genera/species within each of the same, single composition. For example, to conduct a literature search for invention in Group I that is constituted of different chemical structures and mixtures thereof, one would be searching for a total number of combinations that will be a factorial of at least 165 with each one of the ingredients up to ingredient number 1 (i.e. 165\*164, 165\*163, 165\*162, 165\*161, 165\*160, 165\*159, 165\*158, 165\*157, 165\*156, 165\*155,---- 165\*1). Added to this number are the various permutations and combinations of different groups to be added to the chemical structures and bacterial strains. The sum total of all the groups will be a number of geometrical proportions. Therefore, if applicants elect any one of Groups I-IV above, applicants must also make election of species by electing a single species from each of the following categories:

- A. Only one chemical structure with substitutions to said chemical structure among the structures listed in Claims 1, 12-19 and 36;
- B. Only one Group of bacteria among: Gram positive or Gram Negative listed in Claims 3-6 ;
- C. Only one of Bacterial genus and species together with appropriate subspecies strains and sub-strains among those listed in Claims 4, or 6 (e.g., *Mycobacterium bovis* strain BCG and sub-strain thereof);
- D. only one permeability enhancer among those listed in Claims 7-10, especially in Claims 8 and 10;
- E. only one chemical formula among those listed in Claim 20;
- F. Only the chemical structure with substitutions to said chemical structure as listed in Claim 21;
- G. Only one Group of bacteria among: Gram positive or Gram Negative listed in Claims 22 and 24;

- H. Only one of bacterial genus and species together with appropriate subspecies strains and sub-strains among those listed in Claims 23, or in Claim 25 (e.g., *Mycobacterium bovis* strain BCG and sub-strain thereof) ;
  - I. Only the chemical structure with substitutions to said chemical structure as listed in Claim 27;
  - J. Only one Group of bacteria among: Gram positive or Gram Negative listed in Claims 28 and 30;
  - K. Only one of bacterial genus and species together with appropriate subspecies strains and sub-strains among those listed in Claims 29, or in Claim 31 (e.g., *Mycobacterium bovis* strain BCG and sub-strain thereof) ;
  - L. only one permeability enhancer among those listed in Claims 32-35, especially in Claims 33 and 35;
  - M. Only the chemical structure with substitutions to said chemical structure as listed in Claim 37;
  - N. Only one Group of bacteria among: Gram positive or Gram Negative listed in Claims 38 and 40;
  - O. Only one of bacterial genus and species together with appropriate subspecies strains and sub-strains among those listed in Claims 39, or in Claim 41 (e.g., *Mycobacterium bovis* strain BCG and sub-strain thereof).
9. The non-taxonomic species listed above are independent or distinct because claims to the different non-taxonomic species recite the mutually exclusive characteristics of such non-taxonomic species. In addition, these species are not obvious variants of each other based on the current record. Accordingly, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because the inventive groups discussed above incorporate numerous components and numerous ingredients within each of the same, single invention. Therefore, if applicants elect any one of the above-named inventive groups for further prosecution, applicants also need to elect one species categories among A-O listed in preceding paragraph as noted below:

- i. For Group I invention:
  - Only one chemical structure with respective substituents listed in the species category A;
  - Only one bacterial group between those listed in species category B;
  - Only one bacterial genus, species, subspecies, strain and sub-strain as listed in species category C;
  - Only one permeability enhancer among those listed in Claims 8 and 10 as listed in species category D; and
  - only one chemical compound among those listed in Claim 20 as in category E.

ii. For Group II invention:

- Only one chemical structure with respective substituents listed in Claim 21 as noted for the species category F;
- Only one bacterial group between those listed in species category G;
- Only one bacterial genus, species, subspecies, strain and sub-strain as listed in species category H;

iii. For Group III invention:

- Only one chemical structure with respective substituents listed in Claim 27 as listed in the species category I;
- Only one bacterial group between those listed in Claims 28 and 30 as listed in species category J;
- Only one bacterial genus, species, subspecies, strain and sub-strain as listed in species category k;
- Only one permeability enhancer among those listed in Claims 32-35, specially in Claims 33 and 35 as listed in species category L; and

iv. For Group IV invention:

- Only one chemical structure with respective substituents listed in Claim 37 as noted for the species category M;
- Only one bacterial group between those listed in Claims 38 and 40 as noted in species category N;
- Only one bacterial genus, species, subspecies, strain and sub-strain as listed in species category O.

10. Applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merit to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently Claims 1, 21, 27 and 37 are generic claims.

There is an examination and search burden for the above-mentioned patentably distinct species due to their mutually exclusive characteristics. The species require a special field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely raise different non-prior art issues under 35 U.S.C. §101 and or 35 U.S.C. §112, first paragraph.

11. Applicants are advised that the reply to this requirement to be complete must include (i) an election of a species to be examined among the species listed in categories A-O even though the requirement may be traversed (37 CFR §1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable, or that all claims are generic is considered non-responsive unless accompanied by an election.

The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR §1.144. If claims are added after the election, applicant(s) must indicate which of these claims are readable on the elected species.

Should applicants traverse on the ground that the species are not patentably distinct, applicant(s) should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other species. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.

In accordance with 37 CFR §1.499, applicant is required that a reply to this requirement must include an identification of the species that are listed in categories A-O and is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election of a Group and a corresponding species. If claims are added after the election, applicant must indicate which Claims are readable upon the elected species [MPEP §809.02(a)].


12. Applicants are reminded that upon the cancellation of claims to a non-elected invention and species, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).



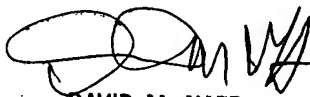
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1657  
(571) 272-0923

05 October 2007

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 128165